15 December 2022
EMA/CHMP/917134/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Fintepla

fenfluramine

On 15 December 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Fintepla. The marketing authorisation holder for this medicinal product is Zogenix ROI Limited.

The CHMP adopted a new indication to add treatment of seizures associated with Lennox-Gastaut syndrome. For information, the full indications will therefore be as follows:[2]

> Fintepla is indicated for the treatment of seizures associated with Dravet syndrome **and Lennox-Gastaut syndrome** as an add-on therapy to other anti-epileptic medicines for patients 2 years of age and older.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold

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